



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

g3734d

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

December 6, 2002

WARNING LETTER
CHI-4-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Alice Glista, Owner
Hobart Laboratories, Inc.
350 N. Ogden Ave.
Chicago, IL 60607

Dear Ms. Glista:

During an August 16, 2002 inspection of your pharmaceutical manufacturing facility, Investigator Jeanne Morris found significant violations of the Federal Food, Drug, and Cosmetic Act (the Act) as they pertain to drug products manufactured in your plant. The violations were presented to Ramon T. Badillo, Production Manager, on the Form FDA 483, Inspectional Observations, at the close of the inspection. A copy of the FDA 483 is enclosed.

Drug products manufactured by your firm are adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice, as set forth in Title 21, Code of Federal Regulations, Part 211. The violations observed regarding your firm's pharmaceutical manufacturing operation included:

- (1) The acceptance criteria for the sampling and testing conducted by the quality control unit (QCU) are not adequate to assure that batches of drug products meet each appropriate specification as a condition for their approval and release, as required by 21 C.F.R. § 211.165(d). For example, during this inspection it was revealed that no data has been collected by your firm to assure that the declared amount of active ingredients (Beechwood Creosote, Guaiacol, and Methyl Salicylate) for two products manufactured by your firm, Numotizine Cataplasm and Numotizine Liniment, meet the amounts declared on the finished product labeling. In addition, the inspection revealed that batch release testing for these two products does not include analytical tests that assure the identity and strength of these active ingredients, as required by 21 C.F.R. § 211.165(a).

- (2) Drug products failing to meet established specifications are not rejected, as required by 21 C.F.R. § 211.165(f). For example, the inspection revealed instances in which lots of Numotizine Cataplast failed to meet final release specifications. Additionally, during the period between 7/30/02 and 9/16/02, [REDACTED] of the lots of Numotizine Cataplast that were manufactured by your firm during this period failed to meet targeted release specifications for thickness. [REDACTED] of these lots were below the specification and [REDACTED] lot was above specification limits. Despite the failure to meet release specifications, these lots were released for distribution by your firm.
- (3) Failure to prepare batch production and control records for each batch of drug product produced, as required by 21 C.F.R. § 211.188. For example, Investigator Morris observed that on 9/12/02, your firm determined that Numotizine Cataplast lot #107-2 did not meet release specifications. After this determination was made, lot #107-2 was reassigned to another batch of Numotizine Cataplast that was still in production and lot number 107-2 was removed from the original batch record for the lot that did not meet specifications.
- (4) Failure to establish and follow procedures that describe the warehousing of pharmaceutical products, as required by 21 C.F.R. § 211.142(a). During the inspection of your firm, Investigator Morris observed pallets of pharmaceutical products that were not labeled to indicate their status. Further investigation revealed that many of these pallets were of lots of product that had been rejected, while lots of product that were in released status were stored with these rejected products.

The above identification of violations, as well as the FDA 483, is not intended to be an all-inclusive list of deficiencies at your firm. You are responsible for ensuring that your firm operates in compliance with the Act and each requirement of the Current Good Manufacturing Practice regulations at 21 C.F.R. § 211. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions may include seizure and/or injunction.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations and prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and specify the time within which the corrections will be completed.

Page 3

Your response should be sent to the attention of George F. Bailey, Compliance Officer at the above address.

Sincerely,

\s\
Arlyn H. Baumgarten
District Director